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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,546	06/04/2007	Romi Barat Singh	RLL-499US	7158

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Ranbaxy Inc.
Intellectual Property Department
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EXAMINER	
MATTISON, LORI K	
ART UNIT	PAPER NUMBER
1619	

NOTIFICATION DATE	DELIVERY MODE
10/17/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

general.ip.mailbox@ranbaxy.com

Office Action Summary	Application No.	Applicant(s)
	10/598,546	SINGH ET AL.
	Examiner	Art Unit
	LORI K. MATTISON	1619

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 July 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/01/2011*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicant's arguments and amendment to claim 1, filed 07/01/2011, are acknowledged and have been fully considered.

2. Claims 1-12 are pending.

Claims 13-18 are cancelled.

Claims 1 and 3 have been amended.

Claims 13-15 are cancelled.

Claims 1-12 have been examined on the merits.

Priority

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Withdrawn Objections/Rejections

4. The objection to the specification is withdrawn due to Applicant's amendment to the abstract.

5. The rejection of claim 3 under 35 USC 112 second ¶ is withdrawn due to Applicant's amendment to the claim.

Maintained Grounds of Rejections

Claim Rejections - 35 USC § 103

6. Claims 1-12 stand rejected under 35 U.S.C. 103(a) as being unpatentable over AMIDON (supplied by Applicant) in view of ARZENO (see Paper No. 20110128), DRUG MONITOR (see Paper No. 20100216), HANCOCK (see Paper No. 20100216), STANIFORTH (see Paper No. 20110128), and VALENTINE (see Paper No. 20110128) (as evidenced by SHARMA (see Paper No. 20110128) and the definition of (see Paper No. 20110128)).

With regard to the newly added claim limitation which requires the solid dosage form to not show conversion of amorphous valganciclovir hydrochloride to crystalline valganciclovir hydrochloride after storage for two months at 40 °C and 75% relative humidity (e.g., see instant claim 1), this property/benefit would result from following the teachings of the prior art. "A general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable." (See *In re Woodruff*, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990)).

Response to Arguments

Applicant argues AMIDON does not teach a dry process because AMIDON utilizes pre-gelatinized starch (Reply, pg. 6, ¶ 2; pg. 12, ¶ 1). Applicant argues pregelatinized starch retains up to 15% moisture and supplies an excerpt from the United States National Formulary which shows the Loss on Drying of 14.0 w/w (Reply, pg. 6, ¶ 2).

In response, Applicant's submission of the excerpt from the United States National Formulary is not evidence. The excerpt for pregelatinized starch from the United States National Formulary clearly states pregelatinized starch is dried (NF 29, pg. 1679, col. 2, "Definition

Section" line 3). As evidenced by the *American Heritage Dictionary of the English Language*, "dried" means "to remove the moisture from. Make dry." Therefore, pregelatinized starch has had the moisture removed from it and therefore the process is a dry process. Notably, the instant disclosure does not contain a definition for the word, "dry."

With regard to Applicant's argument that pregelatinized starch comprises 15% water, it is observed the Loss on Drying Tests appear to be part of tests of forensic tests to identify the substance (see NF 29, pg. 1679, col. 2; pg. 1679, col.1).

Applicant argues pregelatinized starch is not a binder because they did not claim it as a binder, nor does the instant specification teach pregelatinized starch as a binder (Reply, pg. 6, ¶ 2).

In response, as evidenced by Rourke (US Publication No. 2010/0112056), pregelatinized starch is a binder (¶ 37). "From the standpoint of patent law, a compound and all its properties are inseparable." (see M.P.E.P. § 2141.02 V).

Applicant argues the process taught by ARENZO teaches crystalline valganciclovir, with the product being collected by filtration (Reply, pg. 7; pg. 9, ¶ 2; pg. 12, ¶ 1). Applicant argues SHARMA discloses spray drying a solution of valganciclovir hydrochloride to obtain amorphous valganciclovir (Reply, pg. 7). Applicant argues the generalization of "removing the solvent" by the Examiner matters whether a crystalline or amorphous product is obtained (Reply, pg. 7). Applicant argues that isopropanol was added to the mixture to initiate crystallization (Reply, pg. 7).

In response, Applicant's argument is not persuasive. With regard to Applicant's allegation that removal of the solvent via filtration results in a crystalline product, as evidenced

by SHARMA, " The residue obtained is treated with another organic solvent for a time sufficient to precipitate the product which is ***filtered*** and dried 30 under vacuum to get a mixture containing mostly an amorphous form, with some crystalline form of valganciclovir hydrochloride." (SHARMA, pg. 7, lines 28-end; emphasis by the examiner). Thus, Applicant's allegation that filtration does not result in amorphous valganciclovir hydrochloride is not persuasive.

With regard to Applicant's allegation regarding "crystallization initiation," Applicant is directed to pg. 5, last ¶ of Paper No. 20110128 for direction as to what "crystallization" is and how this term is used by the ordinary skilled artisan in the purification arts.

Applicant argues the problem solved by their invention is a way to formulate amorphous valganciclovir hydrochloride while the problem solved by the Examiner is providing valganciclovir with greater bioavailability (pg. 8-pg. 11, ¶ 1; pg. 13, ¶ 3).

In response, the reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant.(See, e.g., *In re Kahn*, 441 F.3d 977, 987, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006)).

Applicant argues the process of their invention results in amorphous valganciclovir hydrochloride which is fine, fluffy, and of relatively low bulk and tap density (Reply, pg. 11, 2).

In response, the teachings of in view of ARZENO, DRUG MONITOR, HANCOCK, STANIFORTH, and VALENTINE teach the claimed process. "A general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable." (See *In re Woodruff*, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990)).

Applicant argues hindsight reasoning was used to reject claims 3-6 and 8 (pg. 12, ¶ 2).

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

With regard to the rejection of instant claims 3-6, the technique taught by VALENTINE is used to produce sustained release formulations. The composition of AMIDON is a sustained release formulation. Thus, the steps taught by VALENTINE are a known technique which may be used to improve similar methods in the same way (i.e. improving the sustained release composition through use of xanthan gum) and are also a known technique to improve a similar method ready for improvement to yield predictable results.

With regard to instant claim 8, as admitted by Applicant, it was known in the art by the ordinary skilled artisan and taught by STANIFORTH that microcrystalline cellulose is a direct compression tableting agent which exhibits superior compressibility and disintegration properties (Reply, pg. 12, ¶ 2). AMIDON is a direct compression method. Therefore, the substitution would have been prima facie obvious to the ordinary skilled artisan.

Applicant argues claims 3-6 are directed to the problem of stability and conversion amorphous valganciclovir to crystalline valganciclovir over time (Reply, pg. 13 ¶ 1)

In response, claim 3-6 are not directed to stability of valganciclovir as alleged by Applicant.

Conclusion

7. **No claims are allowed.**

8. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LORI K. MATTISON whose telephone number is (571)270-5866. The examiner can normally be reached on 8am-6pm (Monday-Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, DAVID BLANCHARD can be reached on (571)272-0827. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LORI K MATTISON/ Ph.D.
Examiner, Art Unit 1619
October 8, 2011
/ROBERT C. HAYES/ Ph.D.
Primary Examiner, Art Unit 1649